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| APPLICATION NO.               | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|---------------|----------------------|---------------------|------------------|
| 09/091,300                    | 06/16/1998    | WOLFGANG VON DEYN    | 5000-0103PUS1       | 4798             |
| 2292                          | 7590          | 01/29/2010           | EXAMINER            |                  |
| BIRCH STEWART KOLASCH & BIRCH |               |                      | HAVLIN, ROBERT H    |                  |
| PO BOX 747                    |               |                      | ART UNIT            | PAPER NUMBER     |
| FALLS CHURCH, VA 22040-0747   |               |                      | 1626                |                  |
| NOTIFICATION DATE             | DELIVERY MODE |                      |                     |                  |
| 01/29/2010                    | ELECTRONIC    |                      |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/091,300             | VON DEYN ET AL.     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | ROBERT HAVLIN          | 1626                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 03 September 2009.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 17, 18, 20-23, 28-31 and 34-52 is/are pending in the application.

4a) Of the above claim(s) 17, 22 and 23 is/are withdrawn from consideration.

5) Claim(s) 21, 28-31, 34-48 and 50-52 is/are allowed.

6) Claim(s) 18 and 49 is/are rejected.

7) Claim(s) 20 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## DETAILED ACTION

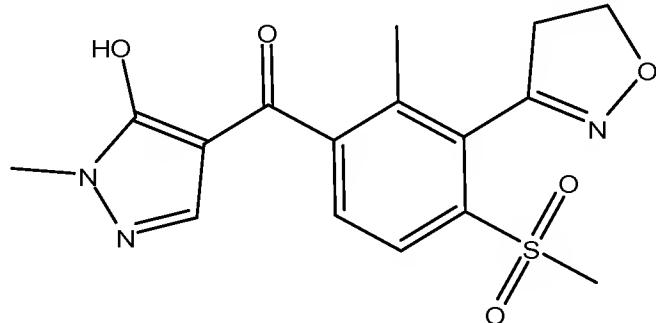
**Status of the claims:** Claims 17, 18, 20-23, 28-31, and 34-52 are currently pending.

**Priority:** This application is a 371 of PCT/EP98/00069 (01/08/1998) and claims foreign priority to GERMANY 197 01 446.1 (01/17/1997). Applicant has provided a translation of the foreign priority document, but a “certified copy of the original foreign application” is not of record as required by 35 USC 119(a-d). Thus, the priority date is that of the filing date until the priority is perfected.

### *Election/Restrictions*

1. During a telephone conversation with Andrew Meikel on 4/14/09 a provisional election was made with traverse to prosecute the invention of the products, claims 18, 20, 21, 28-31, and 34-52.
2. Applicant's affirmation of the election with traverse of Group I (Claims 18, 20, 21, 28-31, and 34-52, drawn to products) in the reply filed on 9/3/09 is acknowledged. The traversal is on the ground(s) that there would not be an undue burden on the examiner. This is not found persuasive because, in addition to the reasons provided in the prior office action, the examination of the groups together would require multiple searches.
3. Applicant also elected the species of claim 30 (reading on claims 21, 28-30, 35-37, 47, 48, 50, 51) having the following structure:

4-[2-Methyl-3-(4,5-dihydroisoxazol-3-yl)-4-methylsulfonylbenzoyl]-1-methyl-5-hydroxy-1H-pyrazole



As detailed in the following rejections, the generic claim encompassing the elected species was not found patentable. Therefore, the provisional election of species is given effect, the examination is restricted to the elected species only, and claims not reading on the elected species are held withdrawn.

Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection through amendment, the amended Markush-type claim will be reexamined to the extent necessary to determine patentability of the Markush-type claim. See MPEP 803.02.

***Double Patenting***

4. Claim 30 of this application conflicted with claim 8 of Application No. 11/739928. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant pointed out distinguishing characteristics due to claim amendments, therefore this rejection is **withdrawn**.

5. Claim 30 was provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 7-9 of copending Application No. 11/739928. Applicant pointed out distinguishing characteristics due to claim amendments, therefore this rejection is **withdrawn**.

6. Claims 21, 28-30, 35-37, 47, 48, 50, 51 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. **7,232,792**. Applicant pointed out distinguishing characteristics due to claim amendments, therefore this rejection is **withdrawn**.

7. Claims 21, 28-30, 35-37, 47, 48, 50, 51 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 7 of U.S. Patent No. **6,613,719**. An approved terminal disclaimer was filed, therefore this rejection is **withdrawn**.

8. Claims 21, 28-30, 35-37, 47, 48, 50, 51 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 13, 16-28 of U.S. Patent No. **6,165,944**. Applicant pointed out distinguishing characteristics due to claim amendments, therefore this rejection is **withdrawn**.

9. Claims 21, 28-30, 35-37, 47, 48, 50, 51 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10 of U.S. Patent No. **7,151,075**. Applicant pointed out distinguishing characteristics due to claim amendments, therefore this rejection is **withdrawn**.

10. Claims 21, 28-30, 35-37, 47, 48, 50, 51 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, and 8 of U.S. Patent No. **6,506,708**. An approved terminal disclaimer was filed, therefore this rejection is **withdrawn**.

11. Claims 21, 28-30, 35-37, 47, 48, 50, 51 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-4, 7-15, and 23-24 of copending Application No. **11/739928**. An approved terminal disclaimer was filed, therefore this rejection is **withdrawn**.

### **NEW CLAIM REJECTIONS**

Applicant has overcome all of the above rejections with claim amendments or by filing an approved terminal disclaimer, thus the examination is hereby expanded beyond

the elected species within the scope of the elected Group I (Claims 18, 20, 21, 28-31, and 34-52, drawn to products).

Regarding the matter concerning the required certified copy of the priority document, the examiner has reviewed the application file for 09/748006 and noticed that there is no “certified copy of the original foreign application” (DE 197 01 446.1) in that application either. See MPEP § 201.14(b). As indicated previously, the application does contain an English translation of the priority document, but this is insufficient to perfect priority. Accordingly, the relevant prior art date for examination is that of US filing.

#### ***Claim Rejections - 35 USC § 112***

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 18 and 49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds identified as readily recognizable as those “radical[s] which can be removed by hydrolysis,” does not reasonably provide enablement for the entirety of the claim scope. The specification does not enable any person skilled in the art to which it pertains to use the invention commensurate in scope with these claims.

Particularly relevant to the instant case is the issue as to whether the specification provides embodiments allowing use of the claimed invention without

requiring undue experimentation by one of ordinary skill in view of the highly unpredictable nature of inhibiting enzymes.

"[An inventor] must not be permitted to achieve . . . dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. That paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Accordingly, the critical element here how broad the claims are compared to the level of unpredictability in the art.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Teletronics*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

*Nature of Invention.* The nature of the invention involves heterocyclic compounds.

*Scope of the Invention.* The scope of the invention are for a large genus of compounds of formula III with a limitation of a "radical which can be removed by hydrolysis," having an infinite number of possible alternatives including those not yet known.

*State of the Art and Level of Skill in the Art.* Although the level of skill in the art is very high, one of skill in the art would have difficulty determining whether a radical would be hydrolyzable in many circumstances.

*Number of Working Examples and Guidance Provided by Applicant.* The applicant provides no working examples and only exemplary language on page 116 of the specification.

*Unpredictability of the Art and Amount of Experimentation.* The art of synthesizing compounds possessing a particular chemical reactivity characteristic given the breadth of the claims is highly unpredictable due to the complex interplay between structural and electronic factors such as steric hindrance. In nearly every case, the skilled artisan could not predict *a priori* whether a given compound would be hydrolyzable. Furthermore, there would be a huge amount of undue experimentation required in order to synthesize and screen the infinite number of compounds within the claimed scope.

Considering the above factors, the claims are not enabled for the full scope of the compounds claimed. The examiner recommends either amending the claim scope to only those compounds closely resembling the compounds actually disclosed in the specification or provide additional data and/or structural correlations to guide one of ordinary skill in the art to those compounds that will possess the claimed chemical reactivity.

#### ***Claims Objections***

Claim 20 is rejected for being dependent on a rejected base claim.

#### ***Conclusion***

The claims are not in condition for allowance. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Examiner, Art Unit 1626

/Rebecca L Anderson/  
Primary Examiner, Art Unit 1626